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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,354	12/31/2003	Gregory Waimong Chan	5618P3473	1158

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/749,354	Applicant(s) CHAN ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-12, 17-19, 21-28, 33-53, 56-58, 63-85, 87, 89-90 and 92-95 is/are pending in the application.
- 4a) Of the above claim(s) 13-16, 29-32, 47-50, 59-62, 88 and 91 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5-12, 17-19, 21-28 and 78-84 is/are allowed.
- 6) ☒ Claim(s) 33-46, 51-53, 56-58, 63-74, 85, 87, 89, 90, and 92-95 is/are rejected.
- 7) ☒ Claim(s) 75-77 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges amended claim 63, cancelled claims 4, 20, 54-55, 86, and 96, and withdrawn claims 13-16, 29-32, 47-50, 59-62, 88 and 91. Currently claims 1-3, 5-12, 17-19, 21-28, 33-46, 51-53, 56-58, 63-85, 87, 89, 90 and 92-95 are currently pending for examination.

Response to Arguments

Applicant's arguments, see Remarks, filed 9/20/2006, with respect to the rejection(s) of claim(s) 1-3, 5-12, 17-19, 21-28, 33-53, 56-58, 63-85, 87, 89, 90 and under Chow et al. (6,692,466) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration and due to the invoking of 35 U.S.C.103(c), a new ground(s) of rejection is made in view of Mirzaee (6,283,947) and Flaherty et al. (US2002/002349).

Allowable Subject Matter/Claim Objections

Claims 1-3, 5-12, 17-19, 21-28, 78-84 are allowed.

Claims 75-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-38 rejected under 35 U.S.C. 102(b) as being anticipated by Mirzaee.

Mirazee discloses a local drug delivery injection catheter.

Regarding claims 33-38, Mirazee discloses an injection catheter comprising an expandable body (32) suitable for percutaneous delivery with at least one delivery cannula (27A-B) coupled to a an exterior portion of the expandable body comprising a plication region with a sheath ring (24,28) that is circumferentially disposed about the at least one delivery cannula proximally adjacent to the plication region wherein the expandable member is a balloon with a working length that can be expanded along the catheter body with multiple lumens that can be used to deliver material (3A-B) all contained within the sheath ring (Figures 4E-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 42-45, 51-53, 56-57, 85, 87 and 89-90 are rejected under 35 U.S.C 103(a) as being unpatentable over Mirzaee in view of Flaherty et al. Mirzaee meets the claim limitations as described above except for the hub and distal needle protuberance.

However, Flaherty et al. teaches systems and methods for delivering drugs to selected locations within the body.

Regarding claims 42-45, 51-53, 56-57, 85, 87, and 89-90, Flaherty et al. discloses an injection catheter that comprises a hub coupled to the catheter body with a protuberance (66) on the needle body that maintains a certain axial location and orientation (Figures 1B-C, 1E).

At the time of the invention, it would have been obvious to add the hub and needle control mechanism of Flaherty et al. to the system of Mirzaee because the addition of a needle depth control system allows for better-controlled injection and treatment of the patient. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Flaherty et al.

Claim Rejections - 35 USC § 103

Claims 39-41, 46, 58, 71 OD are rejected under 35 U.S.C 103(a) as being unpatentable over Mirzaee (or Flaherty et al.).

Mirzaee (or Flaherty et al.) discloses the claimed invention except for adhesive bonding needle angles, and sheath ring distance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the

adhesive bonding, needle angle and sheath ring distance, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 102

Claims 63-70, 72-74, 92 and 94 rejected under 35 U.S.C. 102(b) as being anticipated by Flaherty et al. Flaherty et al. teaches systems and methods for delivering drugs to selected locations within the body.

Regarding claims 63-70, 72-74, 92 and 94, Flaherty et al. discloses a catheter that comprises a first cannula (62) and a second cannula body (64) that comprises (Figure 1E) a superelastic nickel-titanium alloy that is sufficient to be pushed into a patients body through the catheter ([0077]). Flaherty et al. also discloses an injection catheter that comprises a hub coupled to the catheter body with a protuberance (66) on the needle body that maintains a certain axial location and orientation (Figures 1B-C, 1E). Multiple needles are also present in the catheter (Figure 5A). Flaherty et al. also discloses a method for positioning a catheter and maintaining a prescribed orientation and advancing the needle delivery member ([0024-0029]).

Claim Rejections - 35 USC § 103

Claims 93 and 95 are rejected under 35 U.S.C 103(a) as being unpatentable over Flaherty et al. in view of Mirzaee. Flaherty et al. meets the claim limitations as described above except using an expandable member to modify the shape of the catheter assembly.

However, Mirzaee teaches a local drug delivery injection catheter.

Regarding claims 93 and 95, Mirzaee teaches the use of an expandable member to modify the shape of the catheter assembly to deliver agents to the body (col 8).

At the time of the invention, it would have been obvious to add the expandable member and the step of changing the catheter conduit in order to better injection the proper area within the body and allow for better catheter manipulation. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mirzaee.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/22/01


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